

**Examiner's Amendment**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Alan Zamore on March 26, 2010.

Amend claims 12, 13, 16, 18, 21, 26, 32, 38, 39, 40, 44, 45, 47, and 48 as set forth below within the Claim Listing of All Claims.

**Claim Listing of All Claims**

1-11. (Canceled)

12. (Currently Amended) A radiation cross-linkable medical angioplasty balloon or radiation cross-linkable medical catheter made from a thermoplastic cross-linkable composition, said thermoplastic cross-linkable composition comprising: (a) ~~a thermoplastic polymer selected from the group consisting of nylon, a copolyester copolymer of poly(1,4-butanediol terephthalate) and poly(alkylene ether terephthalate), a copoly(ether-ester-amide) polymer, copolymers of polylaurinlactam and polytetrahydrofuran, and a reaction product of an aliphatic polyisocyanate and a polyal~~; and (b) a monomer cross-linker comprising acrylate monomer cross-linkers, said monomer cross-linker present in said composition in an amount sufficient to provide cross-linking of at least a portion of said thermoplastic polymer to convert said portion from a thermoplastic to a thermoset state upon irradiation of said composition with energy from a

Art Unit: 1796

radiation source.

13. (Currently Amended) A radiation cross-linked medical angioplasty balloon or radiation cross-linked medical catheter made by irradiating the radiation cross-linkable medical angioplasty balloon or radiation cross-linkable medical catheter of claim 12 with energy from a radiation source.

14. (Original) The radiation cross-linkable medical angioplasty balloon or radiation cross-linkable medical catheter of claim 12, wherein said thermoplastic polymer is a thermoplastic elastomer.

15. (Original) The radiation cross-linkable medical angioplasty or radiation cross-linkable medical catheter balloon of claim 12, wherein said thermoplastic polymer is a block copolymer containing hard and soft segments.

16. (Currently Amended) The radiation cross-linked medical angioplasty balloon or radiation cross-linked medical catheter of claim 13, wherein said energy is in the form of free radical initiating or ionizing radiation selected from the group consisting of beta particles, gamma particles, ultraviolet radiation, electron beam radiation, and combinations thereof.

17. (Original) The radiation cross-linkable medical angioplasty balloon or radiation cross-linkable medical catheter of claim 12, wherein said monomer cross-linker is

Art Unit: 1796

trimethylolpropane triacrylate.

18. (Currently Amended) A radiation cross-linked medical angioplasty balloon or radiation cross-linked medical catheter made from a cross-linked composition, wherein said cross-linked composition is produced by irradiating a cross-linkable composition comprising: (a) ~~a thermoplastic polymer selected from the group consisting of nylon, a copolyester copolymer of poly(1,4-butanediol terephthalate) and poly(alkylene ether terephthalate), a copoly(ether-ester-amide) polymer, copolymers of polylaurinlactam and polytetrahydrofuran, and a reaction product of an aliphatic polyisocyanate and a polyal~~; and (b) a monomer cross-linker comprising acrylate monomer cross-linkers, said monomer cross-linker present in said composition in an amount sufficient to cross-link at least a portion of said thermoplastic polymer to convert said portion from a thermoplastic to a thermoset state upon irradiation of said composition with energy from a radiation source.

19. (Original) The radiation cross-linked medical angioplasty balloon or radiation cross-linked medical catheter of claim 18, wherein said thermoplastic polymer is a thermoplastic elastomer.

20. (Original) The radiation cross-linked medical angioplasty balloon or radiation cross-linked medical catheter of claim 18, wherein said thermoplastic polymer is a block copolymer containing hard and soft segments.

Art Unit: 1796

21. (Currently Amended) The radiation cross-linked medical angioplasty balloon or radiation cross-linked medical catheter of claim 18, which is produced by irradiating said cross-linkable composition with energy in the form of free radical initiating or ionizing radiation selected from the group consisting of beta particles, gamma particles, ultraviolet radiation, electron beam radiation, and combinations thereof.

22. (Original) The radiation cross-linked medical angioplasty balloon or radiation cross-linked medical catheter of claim 18, wherein said monomer cross-linker is trimethylolpropane triacrylate.

23-25. (Canceled)

26. (Currently Amended) An article suitable for sterilization, surface modification, or surface grafting, comprising

a cross-linked composition, wherein said cross-linked composition is produced by irradiating, with gamma or electron beam radiation, a cross-linkable composition comprising:

(a) ~~a thermoplastic polymer selected from the group consisting of a copolyester copolymer of poly(1,4-butanediol terephthalate) and poly(alkylene ether terephthalate), a copoly(ether-ester-amide) polymer, copolymers of polylaurinlactam and polytetrahydrofuran, and a reaction product of a polyisocyanate and a polyahl, and combinations thereof, wherein the polyamide segments of the copoly(ether-ester-amide) polymer consist of polyamide Nylon 12 segments, and~~

(b) a monomer cross-linker selected from the group consisting of methacrylate monomer cross-linkers, acrylate monomer cross-linkers, and combinations thereof; said monomer cross-linker present in said cross-linkable composition in an amount sufficient to cross-link at least a portion of said thermoplastic polymer to convert said portion from a thermoplastic to a thermoset state upon gamma or electron beam irradiation of said composition with energy from a gamma or electron beam radiation source,

wherein the amount of cross-linked composition is sufficient to increase the tolerance to said sterilization, surface modification or surface grafting of the cross-linked article over that of the article alone without the cross-linked composition.

27. (Original)           The article of claim 26, wherein said article is a medical device.

28. (Previously Presented)   The article of claim 26, wherein said article has been subjected to gamma or electron beam radiation or heat in an amount sufficient to sterilize that article or wherein said article has been subjected to gamma or electron beam radiation in an amount sufficient to graft or modify the surface of that article.

29-31. (Canceled)

32. (Currently Amended)   An wholly or partially encapsulated device, wholly or partially encapsulated with a cross-linked composition produced by irradiating a cross-linkable composition comprising: (a) ~~a thermoplastic polymer selected from the group consisting~~

Art Unit: 1796

~~of nylon, a copolyester copolymer of poly(1,4-butanediol terephthalate) and poly(alkylene ether terephthalate); a copoly(ether-ester-amide) polymer, copolymers of polylaurinlactam and polytetrahydrofuran, and a reaction product of a polyisocyanate and a polyah, and combinations thereof; and (b) a monomer cross-linker selected from the group consisting of allylic monomer cross-linkers, methacrylate monomer cross-linkers, acrylate monomer cross-linkers, and combinations thereof; with the proviso that for the reaction product of a polyisocyanate and a polyah the monomer acrylic or methacrylic cross-linker is other than trimethylolpropane triacrylate, trimethylolpropane trimethacrylate, and triacrylformal; said monomer cross-linker present in said composition in an amount sufficient to provide cross-linking of at least a portion of said thermoplastic polymer from a thermoplastic to a thermoset state upon irradiation of said composition with energy from a radiation source, and wherein the cross-linked encapsulation composition is expanded to a larger size than the device to be encapsulated, by a heating and forming process, and then cooled to retain the expanded size, said expanded cross-linked encapsulation composition possessing the characteristic of "memory" due to the cross-linked polymer comprising the cross-linked encapsulation composition, and wherein the device to be wholly or partially encapsulated is placed within the expanded shaped object with "memory", and wherein heat is applied to cause the expanded cross-linked encapsulation composition with "memory" to contract and wholly or partially encapsulate the device within; with the proviso that when the thermoplastic polymer is nylon, the monomer cross-linker is an acrylate monomer crosslinker, a methacrylate monomer crosslinker, or a combination thereof.~~

Art Unit: 1796

33. (Original)           The device of claim 32, wherein said device is a medical device.

34-37. (Canceled)

38. (Currently Amended)   A wholly or partially encapsulated medical ~~implant~~ device comprising:

    a medical device;

    a radiation cross-linked composition wholly or partially encapsulating said medical device and made by irradiating a radiation cross-linkable composition with energy from a radiation source, the radiation cross-linkable composition comprising:

        (a) ~~a thermoplastic polymer selected from the group consisting of a polyamide elastomer copolymer, nylon, a copolyester copolymer of poly(1,4-butanediol terephthalate) and poly(alkylene ether terephthalate), a copoly(ether-ester-amide) polymer, copolymers of polylaurinlactam and polytetrahydrofuran, a reaction product of a polyisocyanate and a polyah, and combinations thereof, wherein the elastomer is a polyether polymer, a polyester polymer, or a combination thereof; and~~

        (b) a monomer cross-linker selected from the group consisting of allylic monomer cross-linkers, methacrylate monomer cross-linkers, acrylate monomer cross-linkers, and combinations thereof,

        wherein the radiation cross-linked composition is in the form of a heat shrunk shaped object, ~~with the proviso that when the thermoplastic polymer is nylon, the monomer cross-linker is an acrylate monomer crosslinker, a methacrylate monomer crosslinker, or a combination~~

Art Unit: 1796

thereof.

39. (Currently Amended) The wholly or partially encapsulated medical ~~implant~~ device of claim 38, ~~wherein the thermoplastic polymer comprises the copoly(ether-ester-amide) polymer,~~ wherein the polyamide segments of the copoly(ether-ester-amide) polymer consist of polyamide Nylon 12 segments.

40. (Currently Amended) The wholly or partially encapsulated medical ~~implant~~ device of claim 38, wherein the monomer cross-linker is selected from the group consisting of triallylisocyanurate ("TAIC"), triallylcyanurate ("TAC"), and combinations thereof.

41-43. (Canceled)

44. (Currently Amended) A method for producing a thermoset article possessing a shape memory comprising:

irradiating a radiation cross-linkable composition with energy from a radiation source to form a radiation cross-linked composition, the radiation cross-linkable composition comprising

(a) ~~a thermoplastic polymer selected from the group consisting of a polyamide elastomer copolymer, nylon, a copolyester copolymer of poly(1,4-butanediol terephthalate) and poly(alkylene ether terephthalate), a copoly(ether-ester-amide) polymer, copolymers of polylaurinlactam and polytetrahydrofuran, a reaction product of a polyisocyanate and a polyah,~~



Art Unit: 1796

~~and combinations thereof, wherein the elastomer is a polyether polymer, a polyester polymer, or a combination thereof; and~~

(b) a monomer cross-linker selected from the group consisting of allylic monomer cross-linkers, methacrylate monomer cross-linkers, acrylate monomer cross-linkers, and combinations thereof;

heating the radiation cross-linked composition;

expanding the radiation cross-linked composition; and

cooling the radiation cross-linked composition to retain a size obtained in the expanding step;

~~wherein the radiation crosslinked composition shrinks when heated, with the proviso that when the thermoplastic polymer is nylon, the monomer cross-linker is an acrylate monomer crosslinker, a methacrylate monomer crosslinker, or a combination thereof.~~

45. (Currently Amended) The method of claim 44, ~~wherein the thermoplastic polymer comprises the copoly(ether-ester-amide) polymer,~~ wherein the polyamide segments of the copoly(ether-ester-amide) polymer consist of polyamide Nylon 12 segments.

46. (Previously Presented) The method of claim 44, wherein the monomer cross-linker is selected from the group consisting of triallylisocyanurate ("TAIC"), triallylcyanurate ("TAC"), and combinations thereof.

Art Unit: 1796

47. (Currently Amended) A method for forming a wholly or partially encapsulated medical implant device comprising:

providing a medical device;

irradiating a radiation cross-linkable composition with energy from a radiation source to form a radiation cross-linked shaped object, the radiation cross-linkable composition comprising

(a) ~~a thermoplastic polymer selected from the group consisting of a polyamide elastomer copolymer, nylon, a copolyester copolymer of poly(1,4-butanediol terephthalate) and poly(alkylene ether terephthalate), a copoly(ether-ester-amide) polymer, copolymers of polylaurinlactam and polytetrahydrofuran, a reaction product of a polyisocyanate and a polyal, and combinations thereof, wherein the elastomer is a polyether polymer, a polyester polymer, or a combination thereof; and~~

(b) a monomer cross-linker selected from the group consisting of allylic monomer cross-linkers, methacrylate monomer cross-linkers, acrylate monomer cross-linkers, and combinations thereof;

heating the radiation cross-linked shaped object;

expanding the radiation cross-linked shaped object to a size larger than the medical device;

cooling the expanded radiation cross-linked shaped object to retain the size obtained in the expanding step;

placing the medical device within the expanded radiation cross-linked shaped object; and

heating the expanded radiation cross-linked shaped object to shrink the expanded radiation cross-linked shaped object and thereby wholly or partially encapsulate the medical device, with the proviso that when the thermoplastic polymer is nylon, the monomer cross-linker is an acrylate crosslinker, a methacrylate crosslinker, or a combination thereof.

48. (Currently Amended) The method of claim 47, wherein the thermoplastic polymer comprises the copoly(ether-ester-amide) polymer, wherein the polyamide segments of the copoly(ether-ester-amide) polymer consist of polyamide Nylon 12 segments.

49. (Previously Presented) The method of claim 47, wherein the monomer cross-linker is selected from the group consisting of triallylisocyanurate ("TAIC"), triallylcyanurate ("TAC"), and combinations thereof.

Any inquiry concerning this communication should be directed to R. Sergent at telephone number (571) 272-1079.

/Rabon Sergent/  
Primary Examiner, Art Unit 1796